IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER AG, and JANSSEN PHARMACEUTICALS, INC., Plaintiffs, v. ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, AND ALEMBIC PHARMACEUTICALS, INC., Defendants.	C.A. No. 17-675-RGA

ANSWER AND AFFIRMATIVE DEFENSES OF DEFENDANTS ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, AND ALEMBIC PHARMACEUTICALS, INC.

Defendants Alembic Pharmaceuticals Limited ("APL"), Alembic Global Holding SA ("Alembic Global"), and Alembic Pharmaceuticals, Inc. ("Alembic Pharma") (collectively "Alembic" or "Defendants") respond to the numbered paragraphs of the Complaint filed by Plaintiffs Bayer Intellectual Property GmbH, Bayer AG, and Janssen Pharmaceuticals, Inc. (collectively "Plaintiffs") as follows.

Pursuant to Fed. R. Civ. P. 8(b)(3), Alembic denies all allegations in Plaintiffs' Complaint except those specifically admitted below.

NATURE OF THE ACTION

1. Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic admits that Plaintiffs purport to state an action for patent infringement under Title 35 of the United States Code. Alembic admits

that this action relates to an Abbreviated New Drug Application ("ANDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of XARELTO® products prior to the expiration of U.S. Patent No. 9,539,218 and that Alembic submitted the ANDA to the United States Food and Drug Administration ("FDA"). Alembic denies all remaining allegations of paragraph 1.

THE PARTIES

Plaintiffs

2. Alembic lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 2 and therefore denies them.

3. Alembic lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 3 and therefore denies them.

4. Alembic lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 4 and therefore denies them.

Defendants

5. Admitted.

6. Admitted.

7. Admitted.

8. Alembic admits that Alembic Global is a wholly-owned subsidiary of APL. Alembic denies all remaining allegations in paragraph 8.

9. Alembic admits that Alembic Pharma is a wholly-owned subsidiary of Alembic Global. Alembic denies all remaining allegations in paragraph 9.

10. Alembic admits that APL is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products and

that it has filed ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products. Alembic admits that APL has filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patent that may have been alleged to cover such products. Alembic denies all remaining allegations in paragraph 10.

11. Alembic admits that APL prepared and submitted ANDA No. 210301 for APL's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Alembic's ANDA Products"). Alembic denies all remaining allegations in paragraph 11.

12. Alembic admits that APL, Alembic Global, and Alembic Pharma have entered into agreements with one another with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products including in the United States. Alembic denies all remaining allegations in paragraph 12.

13. Alembic admits that APL seeks FDA approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of generic rivaroxaban. To the extent the remaining statements require a response, Alembic denies all remaining allegations in paragraph 13.

14. Alembic admits that APL seeks FDA approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation in the United States of generic rivaroxaban. To the extent the remaining statements require a response, Alembic denies all remaining allegations in paragraph 14.

JURISDICTION

15. Alembic restates and incorporates each of its responses to paragraphs 1-14 as if fully set forth herein.

16. Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic admits that subject matter jurisdiction is proper in this judicial district for the purposes of this action only. Alembic denies all remaining allegations in paragraph 16.

17. Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic admits that Alembic Pharma is a corporation formed under the laws of the state of Delaware. Alembic denies all remaining allegations in paragraph 17.

18. Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic admits that Alembic Pharma has registered to do business in the State of Delaware and has appointed a registered agent in Delaware (National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904) to accept service of process. Alembic denies all remaining allegations in paragraph 18.

19. Alembic admits that Alembic Pharma markets, distributes, offers for sale, and/or sells generic pharmaceutical products for the U.S. market. Alembic denies all remaining allegations in paragraph 19.

20. Alembic admits that Alembic Pharma markets, distributes, offers for sale, and/or sells generic pharmaceutical products in the United States that are manufactured by APL for which APL is the named applicant on approved ANDAs. Alembic denies all remaining allegations in paragraph 20.

21. Paragraph 21 contains legal conclusions and allegations to which no response is required. To the extent an answer may be required, solely for the purposes of this action, Alembic admits that APL has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic ANDA Products in the United States and that Alembic Pharma is planning to market, distribute, offer for sale, and/or sell ANDA Products in the United States upon approval of ANDA No. 210301. Alembic denies all remaining allegations of paragraph 21.

22. Paragraph 22 contains legal conclusions and allegations to which no response is required. To the extent an answer may be required, Alembic lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 22 and therefore denies them.

23. Paragraph 23 contains legal conclusions and allegations to which no response is required. To the extent an answer may be required, Alembic lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 23 and therefore denies them.

24. Alembic admits that it has previously consented to jurisdiction in Delaware, but only on a limited case-by-case basis solely for purposes related to that specific case and that Alembic may have filed counterclaims in such cases. Alembic denies all remaining allegations of paragraph 24.

FACTUAL BACKGROUND

25. Alembic lacks knowledge or information sufficient to form a belief about the truth of all allegations contained in paragraph 25 and therefore denies them.

26. Alembic lacks knowledge or information sufficient to form a belief about the truth of all allegations contained in paragraph 26 and therefore denies them.

27. Alembic admits that U.S. Patent No. 9,539,218 ("the '218 patent") is entitled "Prevention and Treatment of Thromboembolic Disorders" and states on its face that it issued on January 10, 2017. Alembic admits that Exhibit A purports to be a copy of the '218 patent. The remaining allegations of paragraph 27 contain legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic denies them.

28. Alembic admits that claim 1 of the '218 patent states on its face "A method of treating a thromboembolic disorder comprising administering a direct factor Xa inhibitor that is 5-Chloro-N-({(5S)-2-oxo-3-[4-(3-oxo-4-morpholinyl)phenyl]-1,3-oxazolidin-5-yl}methyl)-2-thiophenecarboxamide no more than once daily for at least five consecutive days in a rapid-release tablet to a patient in need thereof, wherein the thromboembolic disorder is selected from the group consisting of pulmonary embolisms, deep vein thromboses, and stroke." Alembic denies all remaining allegations in paragraph 28.

29. Alembic admits that the '218 patent states on its face that it is assigned to BIP. Alembic denies any remaining allegations in paragraph 29.

30. Alembic lacks knowledge or information sufficient to form a belief about the truth of all allegations contained in paragraph 30 and therefore denies them.

31. Alembic lacks knowledge or information sufficient to form a belief about the truth of all allegations contained in paragraph 31 and therefore denies them.

32. Alembic admits that the '218 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO®.

INFRINGEMENT BY ALEMBIC

33. Alembic admits that APL sent to Bayer Intellectual Property GmbH, Bayer Pharma AG, Janssen Pharmaceuticals, Inc., and Christine M. Hansen of Buchanan, Ingersoll & Rooney PC a letter on or about April 21, 2017 (the "Alembic Notice Letter"). The content of the Alembic Notice Letter speaks for itself. Alembic denies the remaining allegations of paragraph 33.

34. The content of the Alembic Notice Letter speaks for itself. Alembic denies the remaining allegations of paragraph 34.

35. The content of the Alembic Notice Letter speaks for itself. Alembic denies the remaining allegations of paragraph 35.

36. The content of Alembic's proposed labeling for its ANDA Products speaks for itself. Alembic denies the remaining allegations of paragraph 36.

37. The content of the Alembic Notice Letter speaks for itself. Alembic denies the remaining allegations of paragraph 37.

38. The allegations of paragraph 38 contain legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic denies them.

39. The content of the Alembic Notice Letter speaks for itself. Alembic denies the remaining allegations of paragraph 39.

40. Alembic admits that it filed ANDA No. 210301 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products as soon as legally permissible. Alembic denies the remaining allegations of paragraph 40.

41. Alembic admits that it filed ANDA No. 210301 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products as soon as legally permissible. Alembic denies the remaining allegations of paragraph 41.

42. Alembic admits that the '218 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO®. Alembic admits that it filed ANDA No. 210301 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products as soon as legally permissible. Alembic denies the remaining allegations of paragraph 42.

43. Alembic admits that it filed ANDA No. 210301 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products as soon as legally permissible. Alembic denies the remaining allegations of paragraph 43.

44. The allegations of paragraph 44 contain legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic denies them.

45. The allegations of paragraph 45 contain legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic denies them.

46. The allegations of paragraph 46 contain legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Alembic denies them.

47. Alembic lacks knowledge or information sufficient to form a belief about the truth of the allegations contained in paragraph 47 and therefore denies them.

CLAIM FOR RELIEF

(Infringement of the '218 Patent)

48. Alembic restates and incorporates each of its responses to paragraphs 1-47 as if fully set forth herein.

49. Alembic admits that it submitted ANDA No. 210301 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products. Alembic otherwise denies the allegations in paragraph 49.

50. Alembic admits that it filed ANDA No. 210301 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products as soon as legally permissible. Alembic denies the remaining allegations of paragraph 50.

51. Alembic admits that it filed ANDA No. 210301 in order to obtain approval under the Federal Food, Drug, and Cosmetic Act to manufacture, use, offer for sale, and/or sale of Alembic's ANDA Products as soon as legally permissible. Alembic denies the remaining allegations of paragraph 51.

52. Denied.

53. Denied.

REQUEST FOR RELIEF

Alembic denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or otherwise.

ALEMBIC'S DEFENSES

Alembic asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise specifically admitted.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY OF U.S. PATENT NO. 9,539,218)

The claims of the '218 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.*, including, *inter* alia, §§ 101, 102, 103, and/or 112, or under other judicially created bases for invalidation.

SECOND AFFIRMATIVE DEFENSE
(NONINFRINGEMENT OF U.S. PATENT NO. 9,539,218)

The manufacture, use, offer for sale, sale, or importation of the products described in Alembic's ANDA No. 210301 do not and will not infringe, directly or indirectly, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '218 patent.

THIRD AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint, in whole and/or part, fails to state a claim upon which relief can be granted.

RESERVATION OF ADDITIONAL AFFIRMATIVE DEFENSES

Alembic reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

PRAYER FOR RELIEF

WHEREFORE, Alembic respectfully requests that this Court enter judgment in its favor and against Plaintiffs:

(a) Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of Alembic's rivaroxaban 10 mg, 15 mg, and 20 mg oral tablets described in Alembic's ANDA 210301 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe,

either directly or indirectly, any valid or enforceable claim of the '218 patent, either literally or under the doctrine of equivalents;

(b) Declaring that the claims of the '218 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. §§ 101, 102, 103 and/or 112;

(c) Ordering that Plaintiffs' Complaint be dismissed, with prejudice, and judgment entered in favor of Alembic;

(d) Declaring this case exceptional and awarding Alembic their reasonable attorneys' fees and costs under 35 U.S.C. § 285;

(e) Ordering that Plaintiffs, and their officers, agents, servants, employees, attorneys, successors, and any person who acts in concert or participation with them, be preliminarily and permanently enjoined from using the '218 patent to block, hamper, hinder, or obstruct FDA approval of the products described in Alembic's ANDA; and

(f) Awarding such other and further relief as the Court may deem just and proper.

/s/ Kelly E. Farnan

Kelly E. Farnan (#4395)
Nicole K. Pedi (#6236)
RICHARDS, LAYTON & FINGER, P.A.
One Rodney Square
920 North King Street
Wilmington, Delaware 19801
302-651-7705
farnan@rlf.com
pedi@rlf.com

Attorneys for Defendants Alembic Pharmaceuticals Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc.

Of Counsel

A. Neal Seth
Karin Hessler
Teresa Summers
Wiley Rein LLP
1776 K St., NW
Washington, D.C. 20036
(202) 719-7000 phone
(202) 719-7049 facsimile
nseth@wileyrein.com
khessler@wileyrein.com
tsummers@wileyrein.com

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